



New Device Approvals

Diomed 630 PDT Laser Model T2USA- P990021

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Diomed 630 PDT Laser Model T2USA
Manufacturer: Diomed, Ltd
Address: 23 Main Street, Suite 240, Andover, Massachusetts 01810
Approval Date: June 30, 2000
Approval Letter: <http://www.fda.gov/cdrh/pdf/p990021a.pdf>

What is it? The Diomed 630 PDT Laser is one part of a treatment system used to treat certain types of cancer. Light from the laser is used to activate a photosensitive drug called Photofrin.

How does it work? The laser light is delivered by a fiber optic system to the area of the body being treated. The fiber optic system and the energy of the laser beam varies depending on the type and location of the cancer.

When is it used? The Diomed Laser is approved to activate the drug Photofrin for the following uses:

- to produce palliation (reduction of symptoms) in patients with partial or complete obstruction of the throat caused by esophageal cancer who do not respond to treatment with a device called a Nd:YAG laser;
- to reduce lung obstructions and symptoms in patients with a type of lung cancer called endobronchial non-small cell lung cancer (NSCLC) and
- to treat bronchial cancer in patients who cannot have surgery or radiotherapy.

What will it accomplish? Light from the laser can activate the drug Photofrin within the cancerous tissue. This can result in complete or partial reduction of the cancer, and with some cancers, its elimination.

When should it not be used? There are no contraindications for use of the laser system. See the package insert for the drug Photofin <http://www.fda.gov/cdrh/pdf/p990021c.pdf> for the appropriate warnings and

a description of the complete procedure.

Additional information:

Summary of Safety and Effectiveness and labeling are available at:

<http://www.fda.gov/cdrh/pdf/p990021.html>

Other:

NIH:

- Select "Photodynamic Therapy" at:
<http://www.nlm.nih.gov/medlineplus/esophagealcancer.html#treatment>
- Lasers in cancer treatment at: http://cis.nci.nih.gov/fact/7_8.htm

American Society for Clinical Oncology:

http://www.asco.org/prof/me/html/98abstracts/lc/m_1782.htm

(Updated 11/27/2001)